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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,848	04/09/2004	Lawrence V. Tannenbaum	CHPPM 03-22 03	8673

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OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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FORT DETRICK, MD 21702-5012

EXAMINER

LIN, JERRY

ART UNIT.	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/820,848

Applicant(s)

TANNENBAUM, LAWRENCE V.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-12 in the reply filed on October 10, 2006 is acknowledged. Furthermore, the Applicant's election without traverse of Species A (sperm count, claim 4) is also acknowledged. The traversal is on the ground(s) that Group II (claim 13) is a narrower process within the scope of Group I (claim 1). This is found persuasive, and the Groups have been rejoined. In light of Group II, Species A-C has also been rejoined with the instant claims. However, Species D remains an unelected invention. It is noted that the species election was mad without traverse.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-6 and 13 are under examination.

Claims 7-12 are withdrawn as being drawn to an unelected species.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Regarding claims 1 and 13, it is unclear to what "receptors" refers. One interpretation of receptors is a protein or other biological product found in a cell. Another interpretation of receptors is an organism living in the site that "receives" the environment. For purposes of this examination, the latter interpretation will be used.
5. Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how comparing the results of the sperm analyses is related to the ecological risk to receptors. The preamble states that the purpose of the method is to determine the ecological risk to receptors. However, the instant claims do not include any step of assessing ecological risk or how ecological risk is a derived form comparing sperm analysis.
6. Instant claim 13, recites the limitation of "two burning pads." It is unclear what this term means. The instant specification does not define the term. A search of the prior art has not revealed any accepted meaning for the term. For purposes of this examination, the Examiner will interpret this term to mean two sites.
7. The term "high" and "low" in claim 13 is a relative term, which renders the claim indefinite. The term "high" and "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328).

The instant claims are drawn to a method for assessing the risk to receptors by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice, comparing the sperm analysis of the mice from the reference site to the sperm analysis of the mice from the contaminated site. It is noted that the claim is unclear as to what "receptors" is referring. For purposes of this Examination, the term "receptors" is interpreted to mean an organism living in the site that "receives" the environment.

Regarding claims 1, 2, 3, and 6, Ieradi et al. teach a method for determining the ecological risk to receptors by obtaining a sample of mice from a contaminated site (page 324, left column); obtaining mice from a reference site (control group) (page 324, left column); performing sperm analysis on all the mice (page 324, left column); comparing the results of the mice (page 324, left column; page 325, figure 1; page 326, left column).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 4, 5, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159).

The instant claims are drawn to a method for assessing the risk to receptors by obtaining rodents from two sites with high hazard quotients for at least one chemical, and a site with low hazard quotients for at least one chemical; removing the vas deferens from rodents to assess sperm motility; removing the epididymis from the rodents to assess sperm count and sperm abnormality; removing the epididymis from the rodents to assess sperm morphology; and comparing the results from the rodents from the different sites. For purposes of this Examination, the term "receptors" is interpreted to mean an organism living in the site that "receives" the environment.

Regarding claims 1 and 13, Ieradi et al. teach a method for determining the ecological risk to receptors by obtaining a sample of mice from two contaminated sites with high hazard quotients (page 324, left column); obtaining mice from a reference site with low hazard quotients (control group) (page 324, left column); assessing sperm abnormality and morphology by obtaining a sample from the epididymis (page 324, left

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column; page 325, figure 1; page 326, left column); comparing the results of the mice (page 324, left column; page 325, figure 1; page 326, left column).

However, Ieradi et al. does not teach removing the vas deferens to assess sperm motility or assessing sperm count.

Regarding claims 4, 5, and 13, Sharma et al. teach a method of determining the toxicity of a chemical in mice by removing the vas deferens and epididymis to assess sperm count and motility (abstract; page 156).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Ieradi et al. and Sharma et al. Ieradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). In particular they are concerned with metals such as lead or mercury (abstract of both). Ieradi et al. states that wild rodents are useful as bioindicators to detect local contamination (page 327, right column). Given that Sharma et al. are concerned with determining the toxic effects of mercury in animal systems (page 153, left column), one of ordinary skill in the art would seek to use a known bioindicator to detect the local contamination of mercury at a particular site. Thus one of ordinary skill in the art would be motivated to combine the methods of Ieradi et al. and Sharma et al. to trap wild mice and conduct the sperm analysis suggested by Ieradi et al. and Sharma et al. to determine the pollution at a site.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

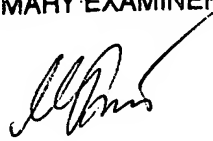
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MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.

JL